

To: Jones, Samantha[Jones.Samantha@epa.gov]; Ross, Mary[Ross.Mary@epa.gov]; Perovich, Gina[Perovich.Gina@epa.gov]; D'Amico, Louis[DAmico.Louis@epa.gov]
From: Berner, Ted
Sent: Thur 6/9/2016 8:14:53 PM
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT
GAO 2008 and 2013 open recs NCEA response to IOAA 6-07-16 track changes v3.docx
NEXGEN RISK ASSESSMENT-FINAL-2014.PDF

Samantha,

OK, I'm going to go ahead and get this back to you.

I incorporated all the information we have regarding examples of "hierarchies" (although, apparently, they don't like to use this term anymore) the various EPA program offices use in identifying alternative tox values.

I found Illa's NextGen report (with Lou's help), but unfortunately it doesn't really contain any information regarding how EPA program offices are currently using NextGen. The report did have a more complete description of what NextGen entails within EPA, and I have now included that in our response. I have attached a copy of the NextGen report in case you want to peruse it yourself.

I have a call in to Annie (as the HHRA Deputy) to see if she can help in responding to Lek's comment, but I haven't heard back. RTP is in the throes of moving today, so she may not be available.

As per Bill Ocampo, when we are satisfied with our responses, we should send them back to the IOAA for final concurrence. Please include Viktoriya Plotkin, Bill Ocampo, and Elizabeth Corona on the distribution. Both Bill and Vik are out of the office tomorrow, but are working AWL. Everyone is aware that this might have to wait until Monday to be finalized since both you and I are out tomorrow, and I don't know what Lek's status is for reviewing it.

-Ted

From: Jones, Samantha
Sent: Thursday, June 09, 2016 1:01 PM
To: Berner, Ted <Berner.Ted@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>

Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT

Ted, can you dig up Ila's report and see if there is anything that could be pulled out. I have included the OW hierarchy (link) and emails with the OAR hierarchy. Ted, can you work with these, and the info Mary got from Kathy R (OLEM) to start adding to the response on alternative sources/data? I've included the latest track changes version (with some additional notes in the comment bubbles based on my conversation with Elizabeth) that needs to continue to show track changes and then we'll clean it up before going forward to IOAA and subsequently Bill.

LINK TO OW HIERARCHY—SEE STARTING ON PAGE 21

<https://www.epa.gov/sites/production/files/2015-10/documents/epa-response-to-public-comments-to-human-health-final-criteria.pdf>

EMAILS WITH OAR ABOUT ALTERNATIVE SOURCES AND NEW DATA

No, we would not consider much outside of IRIS values.

Ines

From: Jones, Samantha
Sent: Wednesday, June 08, 2016 5:37 PM
To: Pagan, Ines <Pagan.Ines@epa.gov>
Subject: RE: quick question about using values other than IRIS

Thank you so much for this and for getting back to me so quickly! Super helpful! I think this answered it, but if I have more questions, I'll give you a call ☺.

I will throw out one more somewhat related question via email...are you all using the newer, alternative toxicity data like those being produced by ORD's CompTox center and CSS?

Thanks again,

Samantha

From: Pagan, Ines

Sent: Wednesday, June 08, 2016 5:28 PM

To: Jones, Samantha <Jones.Samantha@epa.gov>

Subject: RE: quick question about using values other than IRIS

Hi Samantha,

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Ex. 5 - Deliberative Process

If you have further questions feel free to call me ☺

Ines Pagan

From: Jones, Samantha
Sent: Wednesday, June 08, 2016 4:55 PM
To: Pagan, Ines <Pagan.Ines@epa.gov>
Subject: quick question about using values other than IRIS

Hi Ines,

I was talking with Norm Birchfield about situations in which Program Offices need a value and either IRIS doesn't have one or it's a relatively old value such that the program is interested in using another value. He mentioned that OAR has a hierarchy of sorts for these situations. I was wondering if you can share that with me?

I am trying to get caught up on these types of situations across the agency. Additionally, we are getting some questions from ORD IOAA regarding this because the topic came up in a GAO recommendation for IRIS.

Any information you might have pertaining to this would be greatly appreciated! Also, if you have time to chat briefly, that would be good.

Thank you!

Samantha

From: Berner, Ted

Sent: Thursday, June 09, 2016 9:33 AM

To: Jones, Samantha <Jones.Samantha@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>

Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT

Samantha et al.,

I don't have a good mechanism to reach out to the program offices on this topic. I could possibly check with Bob Fegley in OSP to see if he has any insights, or didn't Illa recently author a report on the use of complex data within the Agency? I may have that wrong. Kind of reaching for straws at this point.

So, do we have a plan for finishing this off? Just as an FYI, I'm out tomorrow. I'll update Bill Ocampo on where we are at this point, as I spoke to him yesterday, and we agreed to wait until today to submit our responses to him because Viktoriya was out yesterday.

-Ted

From: Jones, Samantha

Sent: Wednesday, June 08, 2016 10:16 PM

To: Ross, Mary <Ross.Mary@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>

Subject: Fwd: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT

Hi all,

Thanks to a brief conversation with Kacee we found out that Vik was out of the office today, hence her lack of responsiveness to Ted's inquiries. Elizabeth Corona picked up the mantle and talked to Lek about his comments getting further insight. I talked with Elizabeth who clarified the following:

Ex. 5 - Deliberative Process

Thanks,

Samantha

Sent from my iPhone

Begin forwarded message:

From: "Corona, Elizabeth" <Corona.Elizabeth@epa.gov>
Date: June 8, 2016 at 6:08:46 PM EDT
To: "Jones, Samantha" <Jones.Samantha@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT

Thanks.

Were the disciplinary workgroups given guidance on what constitutes low, medium, and high LOE? (time to conduct assessment, FTE, in-house expertise, etc.)

Also, the process document indicated we asked them to provide a qualitative estimate. Did they submit simply a low/med/high ranking, or did we receive the details of what that qualitative estimate is based on?

--

Elizabeth Corona, PhD, MBA

EPA / ORD / Immediate Office

(Desk) 202-564-8356

(Cell) 703-859-2608

From: Jones, Samantha
Sent: Wednesday, June 08, 2016 5:31 PM
To: Corona, Elizabeth <Corona.Elizabeth@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...NCEA DOCUMENTATION FOR LEK'S FIRST COMMENT

Hi Elizabeth!

I was able to talk with Norm about Lek's first question on documentation of our analysis/evaluation supporting the statements about the multi-year agenda and resources needed. I am sending you three files that I think would address Lek's question. I am working on the other question. Let us know if they pass the test 😊 Then we can see if there is anything in the response we need to change.

They are:

1. A Word file (i.e., IRIS MYP process and status – 10-28-14) that provides a summary of the process and categories behind the development of the multi-year agenda
2. An Excel file (i.e., MYP WG ranking consolidated) that provides a breakdown by chemical and the level of effort needed by discipline-specific workgroup. This information includes categorization and ranking and is sorted in various ways and presented in 5 worksheets within this file (e.g., raw, color coded, ranked, sorted by prioritization rank, and numerical average).
3. An Excel file (i.e., MYP Draft v3) that provides the result of the analysis with the list of chemicals selected and their associated level of effort, scores, rank, and program office needs along with anticipated timing and projected completion.

Thanks again for the context and insight into Lek's comments.

Samantha

Samantha J. Jones, Ph.D
Acting Associate Director for Health, ORD/NCEA

Phone: (703) 347-8580

From: Corona, Elizabeth
Sent: Wednesday, June 08, 2016 4:11 PM
To: Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>
Subject: FW: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Hi Mary, Sam, and Lou – Do one of you have a few minutes to chat with me quickly about the responses regarding assessing the level of resources necessary for IRIS and guidance that describes alternative sources of toxicity information?

--
Elizabeth Corona, PhD, MBA

EPA / ORD / Immediate Office

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From: Deener, Kathleen
Sent: Wednesday, June 08, 2016 3:04 PM
To: Corona, Elizabeth <Corona.Elizabeth@epa.gov>
Subject: FW: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

From: Gwinn, Maureen
Sent: Tuesday, June 07, 2016 9:23 PM
To: Jones, Samantha <Jones.Samantha@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Plotkin, Viktoriya <Plotkin.Viktoriya@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Cursio, Heather <Cursio.Heather@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

These look good and seem to address our comments. Thanks for the comment bubbles explaining changes in track change version – very helpful. Adding Vik and Kacee.

I ran the Comptox language by Bob and he is good with it. He is signing off on these as is so as far as he goes, these are good to go.

Vik, do you know if Lek wants to see this again? I think his comments were addressed but the 'scoping and problem formulation' you may want to flag – it was due to a wording issue, which Samantha describes in the track changes version (attached).

I'm signing off now – will be on email somewhat but hoping to not be needed for GAO-related items for the next 6 days...

Thanks –

Maureen

Maureen R. Gwinn, PhD DABT ATS

Special Assistant/IOAA

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m(703)434-9093

From: Jones, Samantha
Sent: Tuesday, June 07, 2016 7:44 PM
To: Gwinn, Maureen <gwinn.maureen@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Hi Maureen,

Here are the draft responses revised to address comments from you, Vik, Lek, Bob, and Kacee. Because it got a little messy, I've attached a clean version and track changes version (which includes notation of the IOAA recent comments).

Thanks and if you think Bob wants to see these again, just let us know. We'll coordinate and then get them over to Bill!

Samantha

Samantha J. Jones, Ph.D
Acting Associate Director for Health, ORD/NCEA

Phone: (703) 347-8580

From: Gwinn, Maureen
Sent: Tuesday, June 07, 2016 10:25 AM
To: Jones, Samantha <Jones.Samantha@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

And to clarify – Bob did not ask to see it again but I can review if it comes back today and let you know for sure if he needs to.

Thanks!

Maureen R. Gwinn, PhD DABT ATS

Special Assistant/IOAA

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From: Jones, Samantha

Sent: Tuesday, June 07, 2016 10:24 AM

To: Berner, Ted <Berner.Ted@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>

Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Hi Ted,

I recommend you go ahead and work on the comments from Maureen. I just looked at Lek's comments and we can address these. I don't think we need to wait until tomorrow to meet and discuss Lek's comments. I'll send some thoughts around via email. We may need to send a response back to Lek to get his reaction, can you check with Vik to see if he wants to see the responses again.

We should finish this today and get it to Bill.

Thanks!

Samantha

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From: Berner, Ted
Sent: Tuesday, June 07, 2016 10:15 AM
To: Gwinn, Maureen <gwinn.maureen@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>
Subject: RE: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Just an FYI, primarily for the NCEA folks (I have added Gina), I just spoke with Maureen to get clarification on a couple of the IOAA comments, which I will try to address today. Maureen thinks that Bob probably doesn't need to see this again.

However, we still have a couple of comments from Lek that we need to deal with, so it may be tomorrow before we get the final version of these responses to Bill for distribution to the OCFO.

-Ted

From: Gwinn, Maureen
Sent: Tuesday, June 07, 2016 9:45 AM
To: Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Ocampo, William <Ocampo.William@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>
Subject: FW: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Sorry, resending to include the NCEA folks.

Maureen

Maureen R. Gwinn, PhD DABT ATS

Special Assistant/IOAA

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From: Gwinn, Maureen

Sent: Tuesday, June 07, 2016 9:44 AM

To: Berner, Ted <Berner.Ted@epa.gov>

Cc: Ocampo, William <Ocampo.William@epa.gov>; Cursio, Heather <Cursio.Heather@epa.gov>; Plotkin, Viktoriya <Plotkin.Viktoriya@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>; Corona, Elizabeth <Corona.Elizabeth@epa.gov>

Subject: FW: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Some comments on the GAO recommendations from Kacee, Bob and me. The revisions received Friday look good and address many of the earlier comments.

Let me know if you have any questions. Just a note – I'm out of the office starting tomorrow and back on the 15th, but I think these should be completed today.

Maureen

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Special Assistant/IOAA

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Ex. 5 - Deliberative Process

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Special Assistant/IOAA

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From: Berner, Ted

Sent: Thursday, June 02, 2016 5:43 PM

To: Gwinn, Maureen <gwinn.maureen@epa.gov>; Plotkin, Viktoriya <Plotkin.Viktoriya@epa.gov>; Corona, Elizabeth <Corona.Elizabeth@epa.gov>; Deener, Kathleen <Deener.Kathleen@epa.gov>

Cc: Cursio, Heather <Cursio.Heather@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>

Subject: Revised draft responses to 2008 and 2013 GAO recommendations for your review...

Maureen and Viktoriya,

Please see attached.

I'm in the office tomorrow if you have any questions.

-Ted